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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,320	01/18/2002	H. Michael Shepard	NB 2019.00	8000

7590 09/22/2004

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EXAMINER

CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/051,320	Applicant(s) SHEPARD, H. MICHAEL	
	Examiner Theodore J. Criares	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) 2,3,5-9 and 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,10 and 13 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/21/04</u> | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 1-22 ARE PRESENTED FOR EXAMINATION

As previously stated claims 2,3,5-9, 12 and 14-22 are withdrawn from consideration and claims 1,4 and 11-13 have been examined only to the extent of the election made by the applicant of phosphoramidatyl deoxyuridine compounds administered to a patient for the treatment of rheumatoid arthritis.

The objection to the specification is withdrawn in view of the applicant's amendment thereto.

Claims 11 is objected to since it fails to clearly set forth applicants' invention of treating rheumatoid arthritis (RA) with phosphoramidatyl deoxyuridine compounds set forth in the specification.. Claims drawn to the administration of these compounds for the treatment of rheumatoid arthritis would advance the prosecution of the subject application.

Applicants' arguments filed May 21, 2004 with respect to claims 1, 4, 12 and 13 have been fully considered but they are not persuasive. .

Applicant's argument at page 4 of the Remarks that, " it **was unknown nor predictive** whether NB 1011 would suppress rheumatoid arthritis and other autoimmune disease", clearly validates the rejection under 35 USC 112, first paragraph. The activity of the p53 gene is unpredictable as evidenced by Rosen et al, (U.S. Patent 6,599,499 B1). At column 1, lines 57-68 it is disclosed that in cancer cells there are

various mutant p53 alleles that would have different growth regulatory properties. Applicants have demonstrated that compound NB 1011 has activity in the treatment of RA. However, since the basis of applicants' invention resides in the activity of the p 53 gene further enablement is deemed necessary to support applicants' claims. It would require undue experimentation by a person skilled in the art to determine what compounds could be administered to treat RA relying on the activity of the gene p 53 which can mutate. .

In view of the above explanation the examiner maintains the rejection under 35 U.S.C. 112 set forth in the previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 10 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for phosphoramidatyl deoxyuridine compounds which fall within the scope of NB 1011, does not reasonably provide enablement for all phosphoramidatyl deoxyuridine compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant admits at page 1, paragraph 0004 to page 2, paragraph 0005 that various biological pathways may be inactivated by tumor suppressing drugs. Applicant's have

provided exemplary evidence that compounds within the scope of NB 1011 provide such an effect when treating rheumatoid arthritis.

Therefor, applicants generic claim to all phosphoramidatyl deoxyuridine is deemed to be beyond the scope of the enabled disclosure of the specification.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Theodore J. Criares
Primary Examiner
Art Unit 1617

TJC
9/17/04